

Appl. No. 10/026,753
Amdt. dated September 5, 2006
Reply to Office Action of March 2, 2006

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REMARKS

The Invention.

The present invention provides a process for liquefying starch using an alpha-amylase enzyme obtained from *Bacillus acidocaldarius* species at a low pH without the need to add bisulfite or thermostabilizing agents such as calcium. Specifically, the invention relates to starch hydrolysis processes that do not require a secondary liquefaction step or pH adjustments before and after liquefaction.

Status of the Application.

Claims 1, 2, 6-18, 21-34, 37-51 and 53-61 are pending in the application. Applicants reserve the right to file further continuation applications on any subject matter disclosed in the instant application or on the subject matter of any previously or presently cancelled claim. Claim 1 has been amended to correct grammatical errors. Claim 17 has been amended to more clearly state what Applicants believe is the invention. Applicants assert no new matter has been introduced by the amendment.

Rejection under 35 U.S.C. §102(b)/103 -

35 U.S.C. §102(b).

It is well-settled law that to anticipate a claim the prior art reference must contain each and every element within the four corners of the document. Thus, Applicants submit that there can be no anticipation unless all of the same elements of the invention are found within the four corners of a single reference. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 USPQ2d 1766, 1767-68 (Fed. Cir. 1987). A reference that merely contains substantially the same elements or only broadly teaches the invention is insufficient to establish anticipation. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 756 F.2d 1556, 1560, 225 USPQ 253, 256 (Fed. Cir. 1985).

Claims 47-51

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Claims 47-51 stand rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative under 35 U.S.C. §103 (a) as obvious over Antrim *et al.* (US Pat. No. 5,322,778). Applicant respectfully traverses the rejection.

Applicants have amended claim 17. Thus, the products produced by the process are not identical.

Given the strict standards for anticipation, it is readily apparent that there is no anticipation of the claimed invention in view of Antrim *et al.* Withdrawal of the rejection is respectfully requested.

Claims 46-51

Product by process claims 46-51 stand rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative under 35 U.S.C. §103 (a) as obvious over Liaw *et al.* (US Pat. No. 6,136,571). Applicant respectfully traverses the rejection.

The Examiner points to Col. 1, line 61 through Col. 2, line 10 as disclosing a liquefied starch product which appears to be identical to the presently claimed product. Applicants respectfully disagree. Initially, Applicants point out that the currently claimed process is conducted at a pH of between 3.0 and 4.5, whereas the Liaw *et al.* process is done at a pH of between 5.5 and 6.0 (see Col. 1, line 67). Applicants at page 2, lines 25-27, state "The high pH requirement results in undesirable by-products, e.g., maltulose which ultimately lowers glucose yields." Therefore, Applicants respectfully submit that the compositions are not the same. Withdrawal of the rejection is respectfully requested.

35 U.S.C. §103.

A *prima facie* case of obviousness requires the Examiner to cite to a combination of references which (a) suggests or motivates one of skill in the art to modify their teachings to yield the claimed invention, (b) discloses the elements of the claimed invention, and (c) provides a reasonable expectation of success should the claimed invention be carried out. Failure to establish any one of these

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requirements precludes a finding of a *prima facie* case of obviousness and, without more, entitles Applicants to withdrawal of the rejection of the claims in issue.¹

Claims 1, 2, 6-18, 21-34 and 37-51 – 52

Claims 1, 2, 6-18, 21-34 and 37-51 – 52 as allegedly obvious over the combination of Shetty in view of JP10-136979 (JP '979). Specifically the Examiner asserts the process parameters suggested by Shetty *et al.* "Factors Affecting the Economics of Glucose Production", Delivering Innovation Through Biotechnology", Genencor International, Inc. (1998) (Shetty) as being desirable provide the motivation to the skilled artisan to use the enzyme of JP '979. Applicants respectfully traverse.

Applicants believe that, at best, the Examiner presents an "obvious to try" standard in determining the patentability of the present invention, a standard which has been thoroughly discredited. Although Shetty suggests which parameters it would be desirable to change it gives no indication as to *how* the skilled artisan may be able to achieve the desired results. In order to establish a *prima facie* case of obviousness the reference must provide sufficient basis for the required expectation of success; this is completely lacking in Shetty.

Applicants note that the process described by Shetty and/or JP '979 is not the same as that presently claimed by the Applicants nor would combining the two result in the presently claimed process. First, Shetty teaches away from the presently claimed pH conditions of between 3.0 and 4.5 on page 7 ("Values of lower than pH 6.2 to 6.4 decrease the reaction rate and the stability of the *Bacillus licheniformis* alpha-amylase...").

Second, as previously presented, Shetty describes a two-stage liquefaction process. See page 5 of Shetty where the "Secondary Liquefaction Reactors" are noted and the addition of an alpha-amylase is shown twice. The current claims recite "with a single addition of a thermostable, acid-stable alpha-amylase". There is no teaching that a single addition of an alpha-amylase could or should be used.

¹ See e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990); and *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988).

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Third, as noted by Shetty on page 6, the liquefaction step is carried out at pH 6.0 to 6.5, whereas the currently claimed process is conducted at a pH of from 3.5 to 4.5. Furthermore, although Shetty provides that it is desirable to achieve a DE of 10 to 12, there is no teaching that such a DE would be obtained when the liquefaction step was conducted at a pH of from 3.5 to 4.5. Indeed, Figure 12 on page 14 of Shetty shows that a DE of 10 is not achieved even after 120 minutes at pH 5.0.

Thus, while Shetty may describe a desired amylase on page 11, it is completely silent on what that amylase would be, how to find it, how to use it or any other technical aspects of the amylase and its use in liquefaction as a single addition (of the alpha-amylase). Therefore, Shetty is a mere invitation to try.

Recognizing one of the deficiencies of Shetty, the Examiner has cited JP10-136979 as teaching the *Bacillus acidocaldarius* (KTSM #2037). However, it is submitted that JP 10-136979 in combination with Shetty does not suggest to one skilled in the art that the single addition of an alpha-amylase obtained from *Bacillus acidocaldarius* (KTSM #2037) could be used in a liquefaction process wherein a DE of about 10 – 12 is obtained within 60 to 75 minutes of adding the alpha amylase nor that the pH of the starch solution would not have to be adjusted prior to or after the addition of the alpha amylase to be useful for saccharification. *In fact, the English translation of JP '979 (kindly provided by the Examiner) states at paragraph [0063] that the alpha-amylase is added after the slurry's pH is adjusted to 4.5.* As stated repeatedly in the present disclosure, the liquefaction step does not require pH adjustment of the starch slurry prior to enzymatic liquefaction (see, for example, page 3, lines 13-14) and further less time is required to produce a liquefact with a commercially acceptable DE value (see page 4, lines 13 – 16 and page 5, lines 13 - 19). Moreover, the claimed invention does not require the adjustment of the slurry's pH prior to adding the amylase.

The JP '979 application also fails to describe a single addition of the alpha-amylase. In fact, the English translation of JP '979 states, just as Shetty discloses (see Figure 3 on page 5 of Shetty), that the alpha-amylase is added after the slurry is cooled. See Example 3 of the JP '979 application. Thus, both Shetty and JP '979 both add alpha-amylase in a two-step starch liquefaction process (i.e., alpha-

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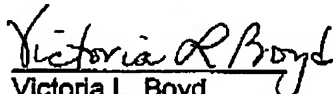
amylase is added at two time points in the liquefaction process). Furthermore, *there is nothing in either Shetty or JP '979 that would lead the skilled artisan to use a single dose of alpha-amylase with the expectation that acceptable DE amounts in a single low (or high) temperature liquefaction step would be achieved.* Therefore, JP '979 fails to correct the deficiencies of Shetty and the combination fails to render obvious the present invention. Withdrawal of the rejection is respectfully requested.

Applicants assert not only is the process patentable over the cited art but also the claimed starch liquefact product is novel and unobvious over the cited art. Withdrawal of the rejection is respectfully requested.

CONCLUSION

In light of the above amendments, as well as the remarks, the Applicants believe the pending claims are in condition for allowance and issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (650) 846-7615.

Respectfully submitted,
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Date: September 5, 2006

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GC695 ROA 09-05-08